

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

In re:)	
PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE)	MDL No. 1456
LITIGATION)	
)	Civil Action No. 01-12257-PBS
)	
)	Subcategory No. 06-11337
THIS DOCUMENT RELATES TO:		
)	
<i>United States ex rel Ven-A-Care of the</i>)	
<i>Florida Keys, Inc. v. Schering Corporation,</i>)	Hon. Patti B. Saris
<i>Schering-Plough Corporation and</i>)	
<i>Warrick Pharmaceuticals Corporation</i>)	
Civil Action No. 09-CV-10547)	
)	
<i>United States ex rel Ven-A-Care of the</i>)	
<i>Florida Keys, Inc. v. Schering Corporation,</i>)	
<i>Schering-Plough Corporation and</i>)	
<i>Warrick Pharmaceuticals Corporation</i>)	
Civil Action No. 00-10698)	

**THE COMMONWEALTH'S RESPONSE
TO THE SCHERING/WARRICK DEFENDANTS'
MEMORANDUM ON NON-PARTY CLAIM PRECLUSION**

Introduction

On August 7, 2009 the Schering/Warrick defendants¹, along with California, Florida and the Relator, filed a Settlement Agreement and Release with the Court for approval. Among other things, this settlement agreement purported to release “the federal share of any claim brought by a state arising out of or related to the Covered Conduct or Covered Drugs.” Settlement Agreement and Release, Dkt. No. 6173-2, p.8, ¶5. The Commonwealth of Massachusetts moved to intervene in these cases for the limited purpose of opposing approval of that Settlement Agreement. (Dkt. No. 6275.) The

¹ The Schering/Warrick defendants are Schering-Plough Corporation, Schering Corporation and Warrick Pharmaceuticals Corporation.

United States, other states and certain New York local governments also objected. After extensive briefing from the objectors, Schering /Warrick entered into further settlement discussions with the United States. On December 7, 2009 Schering/Warrick filed with the Court a revised Settlement Agreement and Release and a proposed Order of Dismissal. (Dkt. No. 6743-2 and 6743-5.) The United States has filed its consent to the revised Settlement Agreement and Order of Dismissal. (Dkt. No. 6746.)

The Commonwealth raised four objections to the original agreement: (1) the Attorney General had not consented; (2) the relator could not release any portion of the Commonwealth's case; (3) the settlement required the Court to issue advisory opinions; and (4) the settlement terms were neither fair, adequate nor reasonable. (Dkt. No. 6457.) The revised agreement resolves three of those objections: (1) the Attorney General has now consented; (2) the advisory opinions have been removed; and (3) the settlement amount has been increased and the Attorney General has deemed the amount the United States will receive "fair, adequate and reasonable ... under all the circumstances." (Dkt. No. 6746, p.2.)

The revised Settlement Agreement and the proposed Order of Dismissal continue, however, to contain language which purports, on its face, to release a portion of the Commonwealth's case against Schering/Warrick:

This Order fully, finally, and forever resolves all claims related to the federal share (defined to mean that portion of Medicaid expenditures paid by the United States) of any Medicaid overpayment allegedly arising out of the Covered Conduct or the price reporting for reimbursement purposes for the Covered Drugs, *including but not limited to the federal-share of any claim brought by a state arising out of or related to the Covered Conduct or the price reporting for reimbursement purposes for Covered Drugs consistent with the principles of claim preclusion set forth in Taylor v. Sturgell, 553 U.S. __, 128 S.Ct. 2161 (2008) and Giragosian v. Ryan, 547 F.3d 59 (1st Cir. 2008).*

Proposed Order of Dismissal. Dkt. No. 6743-5, p.4, ¶ 2 (emphasis added). See also, Settlement Agreement, Dkt. No. 6743-2, p.10, ¶ 4. In support of this language, and in response to the Commonwealth's Sur-Reply Memorandum (Dkt. No. 6503) and Supplemental Sur-Reply Memorandum (Dkt. No. 6565), Schering/Warrick has submitted a brief addressing the law of claim preclusion and purporting to justify this quoted language. (Dkt. No. 6744.)

As set forth below, the Commonwealth believes that Schering/Warrick is just wrong on the law of claim preclusion. The Commonwealth is not objecting, however, to the Court approving the revised Settlement Agreement. This revised settlement agreement will help mitigate the harm caused by Schering/Warrick's price reporting policies. Two states and the federal government will receive a substantial amount of badly needed money and this Court will reduce its AWP MDL caseload.

The Commonwealth believes that the preclusive effect, if any, of the proposed Order of Dismissal, against the Commonwealth, is not presently ripe for adjudication in this proceeding. The Commonwealth has received assurances from the federal government that if the Commonwealth chooses to pursue only those damages which were not reimbursed by the federal government, the federal government will not seek any portion of any recovery obtained. On the other hand, if the Commonwealth seeks all of the damages caused by Schering/Warrick's conduct, then the federal government expects to share in any recovery received. The division of such proceeds would be 60/40, because Massachusetts has a Deficit Reduction Act (DRA) qualifying False Claims Act. The federal government has also advised the Commonwealth that if it seeks "state-only" damages, and makes a recovery, the federal government will make a DRA bonus

payment to the Commonwealth from the federal settlement in these cases. Such DRA bonus payment is likely to be substantially less than what the Commonwealth could recover in its own case, seeking all the damages caused by Schering/Warrick, even giving Schering/Warrick an offset for that portion of what it pays the federal government in these cases which is attributable to MA claims.

Given these developments, the Commonwealth has not decided whether it will seek all of the damages caused by Schering/Warrick , or it will seek only those damages which were not reimbursed by the federal government. Claim preclusion is an affirmative defense. It will arise only if the Commonwealth seeks to recover all of the damages. Thus, it is not clear whether this Court will ever have to address Schering/Warrick's assertion of claim preclusion relating to this settlement.

ARGUMENT

Schering/Warrick Has Failed To Show That Any Judgment In These Cases Will Have Any Preclusive Effect Against The Commonwealth - A Nonparty

In the First Circuit the basic rule is that claim preclusion requires consideration of “the finality of the judgement, the identity of the parties and the identity of the causes of action.” Herman v. Meiselman, 541 F.3d 59, 62 (1st Cir. 2008); Giragosian v. Ryan, 547 F.3d 59, 63 (1st Cir. 2008). Since there is no “identity of parties” between these federal *qui tam* actions and Commonwealth’s case, there can be no claim preclusion here pursuant to the basic rule.

Extending the preclusive effect of a judgment to a nonparty runs up against “the deep-rooted historic tradition that everyone should have his own day in court.” *Taylor v. Sturgell*, __U.S.__, 128 S.Ct. 2161, 2164, 171 L.Ed.2d 155 (2008) (*quoting Richards v.*

Jefferson County, 517 U.S. 793, 798, 116 S.Ct. 1761, 135 L.Ed.2d 76 (1996)). Thus, the general rule is that one is not bound by a judgment *in personam* in a litigation in which he is not designated as a party or to which he has not been made a party by service of process. *Id.* There are, however, narrow, discrete, limited exceptions to this rule.

Claim preclusion is an affirmative defense for which the defendant must prove all necessary elements. *Id.* at 2180. In *Taylor v. Sturgell*, the United States Supreme Court recognized there are six discrete, limited exceptions to the fundamental rule that a litigant is not bound by a judgment to which he was not a party. *Id.* at 2172. These non-party claim preclusion exceptions are: (1) the non-party agreed to be bound by the determination of issues in the first action; (2) there is a pre-existing substantive legal relationship between the non-party and a party to the judgment; (3) the non-party was adequately represented by someone with the same interests who was a party to the prior suit; (4) the non-party assumed control over the litigation in which that judgment was rendered; (5) the non-party brings the second suit as the designated representative of a person who was a party to the prior adjudication; and (6) a special statutory scheme otherwise consistent with due process expressly forecloses successive litigation by nonlitigants. *Id.* at 2172-73. Schering/Warrick argues, incorrectly, that three of these exceptions apply to this case. (Dkt. No. 6744, pp. 5-9.)

1. “Pre-existing substantive legal relationship” between party and non-party

First, Schering/Warrick claims that the joint federal/state nature of the Medicaid program creates a “pre-existing substantive legal relationship” between the federal government and the states that justifies precluding claims brought by the Commonwealth. (Dkt. No. 6744, pp.5-6.) Not just any legal relationship, however, will subject a non-party

to claim preclusion under this exception. This exception “does not embrace mere close relationships between a party and non-parties.” 18A Wright & Miller, Federal Practice & Procedure § 4448 (2d ed. 2002). The Court in *Taylor* specifically illustrated the types of substantive legal relationships in which this exception applies: preceding and succeeding owners of property, assignors and assignees², and bailors and bailees. *Taylor*, 128 S.Ct. at 2172; Restatement (Second) Judgments §§ 43-44, 52, 55. This exception also applies to traditional private and official appointments: trustees, executors, guardians and statutory representatives in death and survival actions. 18A Wright & Miller, Federal Practice & Procedure § 4448. The Supreme Court in *Taylor*, in rejecting a “fact-driven” and “equitable” inquiry as to when a relationship is “close enough” so that a non-party is bound by the judgment against a party in a prior action, said “our decisions emphasize the fundamental nature of the general rule that a litigant is not bound by a judgment to which she was not a party.” *Taylor*, 128 S.Ct. at 2174-75.

There is no authority to support Schering/Warrick’s assertion that the relationship between the federal and state governments in the context of the Medicaid program is “close enough” to qualify as a “pre-existing substantive legal relationship” justifying complete disregard for the fundamental rule against non-party claim preclusion. The types of relationships contemplated in this exception are different from the relationship between state and federal governments in Medicaid. Executors, trustees, guardians, and assignees effectively step into the shoes of a non-party to litigate the non-party’s claim.

² In an obvious attempt to confuse the issue, Schering argues that the relator acts as “an assignee” of the United States in a federal qui tam action, and the assignor-assignee relationship is one of the “qualifying relationships” included among the *Taylor* exceptions. Clearly, this argument fails. It is the relationship between the party in the first action and the non-party in the second action that is relevant. The Commonwealth’s relationship to the parties in the Ven-a-Care litigation is at issue, not the relationship between Ven-a-Care and the United States.

Neither Ven-A-Care nor the United States ever stepped into the Commonwealth's shoes to litigate its case.

2. The non-party was “adequately represented by someone with the same interests”

“In certain limited circumstances,” a nonparty may be bound by a judgment because she was “adequately represented by someone with the same interests who [wa]s a party” to the suit. *Taylor* at 2172 (*quoting Richards v. Jefferson County*, 517 U.S. 793, 798, 116 S.Ct. 1761(1996)). Representative suits with preclusive effect on nonparties include properly conducted class actions, and suits brought by trustees, guardians, and other fiduciaries. *Id.* at 2172-73 (*citing Martin v. Wilks*, 490 U.S. 755, 762, n.2, 109 S.Ct. 2180, 104 L.Ed2d 835 (1989); *Sea-Land Svcs., Inc. v. Gaudet*, 414 U.S. 573, 593, 94 S.Ct. 806, 39 L.Ed2d 9 (1974); 1 Restatement § 41).

A party's representation of a nonparty is “adequate” for preclusion purposes only if, at a minimum: (1) the interests of the nonparty and her representative are aligned, and (2) either the party understood herself to be acting in a representative capacity or the original court took care to protect the nonparty's interests. *Taylor*, 128 S.Ct. at 2174. The interests of the parties are aligned and due process is protected where the party who is present is “entitled to stand in judgment for those who are not.” *Hansberry v. Lee*, 311 U.S. 32, 43, 61 S.Ct. 115 (1940). A party cannot stand in judgment for a non-party where the two have “dual and potentially conflicting interests.” *Id.* at 44; *see also Richards*, 517 U.S. at 801-802, 116 S.Ct. 1761.

Ven-A-Care, as the relator, clearly cannot stand in judgment for the Commonwealth. As a relator, Ven-A-Care's interests are different and potentially conflicting with those of the Commonwealth. A relator in a *qui tam* action has personal

interests which can direct its actions, both in the litigation and in settlement. *See Searcy v. Philips Electronics North America Corp.*, 117 F.3d 154, 160 (5th Cir. 1997). In connection with this settlement Ven-A-Care and the Commonwealth have been actual adversaries. In addition, the Commonwealth was excluded from the settlement discussions which resulted in the revised Settlement Agreement. Contrary to Schering/Warrick's contention, it is not sufficient that a party and non-party may have some interest in common. Their overall interests must be "aligned."

Moreover, even if Ven-A-Care's and Massachusetts's interests were "aligned," which the Commonwealth denies, there is no indication that Ven-A-Care understood itself to be acting as a representative of Massachusetts or that the rights and interests of Massachusetts were considered throughout the course of the Schering/Warrick/Ven-A-Care litigation. *See Taylor*, 128 S.Ct. at 2174-75.

3. Non-party as "Designated representative" of prior party

Finally, Schering/Warrick argues that Massachusetts is a designated representative of the United States. Dkt No. 6744, pp.8-9. The applicable *Taylor* exception is "a party bound by a judgment may not avoid its preclusive force by relitigating through a proxy." 128 S.Ct. at 2179. Ultimately, the Court in *Taylor* remanded the case so the lower courts could examine whether there was an agency relationship between the non-party and the party in the prior action. However, the *Taylor* Court warned that "courts should be cautious about finding preclusion on the basis of agency." *Id.* The Court elaborated:

A mere whiff of "tactical maneuvering" will not suffice; instead, principles of agency law are suggestive. They indicate that preclusion is appropriate only if the putative agent's conduct of the suit is subject to the control of the party who is bound by the prior adjudication. See 1

Restatement (Second) of Agency § 14, p. 60 (1957)(“A principal has the right to control the conduct of the agent with respect to matter entrusted to him.”) *Id.*

In order for the Court to find preclusion on the basis of agency, the Court must find that the Commonwealth’s conduct in its own litigation is subject to the control of the United States or Ven-A-Care. As set forth in the Commonwealth’s Sur-Reply Memorandum, and left undisputed by Schering/Warrick, there is no evidence that the Commonwealth’s conduct in its litigation has been subject to the control of Ven-A-Care or the United States. Certainly there is no evidence that the relator or the United States participated in decisions regarding whom to sue, on what drugs, what discovery to take, what legal positions to argue, what evidence to present at trial or whether to accept settlement offers. There certainly is no evidence that Ven-A-Care or the United States will be controlling the Commonwealth’s case going forward. Schering/Warrick has simply not met its burden of establishing that the Commonwealth is acting as a proxy for Ven-A-Care or the United States.

CONCLUSION

The Commonwealth is not objecting to the Court approving the revised Settlement Agreement and entering the proposed Order of Dismissal. Schering/Warrick has failed to carry its burden of demonstrating that the relationship among Ven-A-Care, the United States and the Commonwealth with regard to these cases will comply with any of the six narrow, discrete, exceptions to the general rule that claim preclusion does not run to non-parties, so as to give preclusive effect to the proposed Order of Dismissal, as against the Commonwealth. The Order, by its express terms, resolves the “federal-share” of any claim brought by a state only to the extent “consistent with the principles of claim

preclusion set forth in *Taylor v. Sturgell*, 553 U.S. ___, 128 S.Ct. 2161 (2008) and *Giragosian v. Ryan*, 547 F.3d 59 (1st Cir. 2008). As set forth above, these two cases provide no basis to preclude the Commonwealth from pursuing its full damages, if it so chooses.

Respectfully submitted,

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Dated: December 10, 2009

Certificate of Service

I hereby certify that a copy of the foregoing Commonwealth's Response to the Schering/Warrick Defendants' Memorandum on Non-Party Claim Preclusion was served on counsel for each other party in this action by filing it electronically in the Court's CM/ECF system, this 10th day of December, 2009.

/s/ Peter A. Mullin
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